

## REMARKS

Initially, the Applicant notes the Examiner's request to present the Abstract in proper domestic form. Applicant presumes this means to include it at the end of the application. Applicant has provided a substitute Abstract for the application which Applicant believes conforms to US practice. Should the Examiner disagree, Applicant respectfully requests the Examiner to provide more detail in how to provide an Abstract the Examiner believes to be acceptable. In the meantime, Applicant respectfully request that this substituted Abstract be entered.

Next, the Examiner has rejected claims 40-50 as non-enabling with respect to preventing a pelvic tissue infection. All reference to prevention of such an infection has been deleted from the claims. Thus, the rejection to lack of enablement is believed to now be moot.

Furthermore, claims 34-39 have been cancelled. Accordingly, the rejections with respect to claims 34-35 and 37-39 is also believed to now be moot.

Finally, the Examiner has rejected pending claims 40-50 as being unpatentable over Herschler U.S. Patent No. 4,997,823 in combination with Kelly WIPO Publication No. WO 02/092097 A1 and in combination with Pena *et al.* WIPO Publication No. WO 02/072066. Applicant has reviewed the rejection and believe that the claims as now presented overcome the rejection and patentably distinct from the cited prior art in this rejection.

Independent claims 40 and 44 have been limited to administering vaginally a therapeutically effective amount of an antibiotic and of a prostaglandin to a patient in need of such treatment wherein the antibiotic is azithromycin. The Examiner has herself acknowledged that none of Herschler, Kelly and Pena *et al.* discloses vaginal administration of an antibiotic such as azithromycin. This can be seen because Pena *et al.* only mentions azithromycin because it is said to be sufficiently absorbed when administered rectally in co-therapy or coformulation with one or more oxazolidinone antibiotics (see page 9 lines 13-29). From page 8 lines 20-23 of Pena *et al.*, it is clear that the disclosed rectal administration of an antibiotic is for treatment of a systemic infection because it is stated that "a large part of the total concentration of oxazolidinone in the composition is absorbed into systemic circulation following rectal administration" (emphasis added). Accordingly, Pena *et al.* does not disclose use of azithromycin for vaginal administration or for the treatment of a tissue infection local to the area of application, e.g. a pelvic tissue infection. In the absence of disclosure of vaginal

administration of azithromycin and its use in the treatment of a pelvic tissue infection in the cited prior art documents, it cannot be argued that the present invention is obvious from those documents.

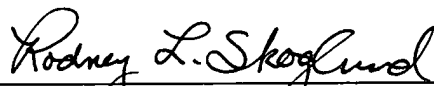
Furthermore, it is noted that Kelly discloses the use of a prostaglandin in a method of inducing cervical ripening in a patient. The aims of such a use of a prostaglandin are set out at page 19 lines 8 to 25 from which it can be seen that there is no disclosure or suggestion in Kelly of the use of a prostaglandin in the treatment of a pelvic tissue infection. For these reasons, it is respectfully submitted that the pending claims are not obvious over Herschler in combination with Kelly and in combination with Pena *et al.*

Applicant has added four (4) new claims that each depend either directly or indirectly from claim 40. Consequently, these new claims are believed allowable.

In light of the foregoing, reconsideration of all pending claims 40-54 is respectfully requested, and a Notice of Allowance of those claims is earnestly solicited. Should the Examiner wish to discuss any of the foregoing in greater detail, the undersigned attorney would welcome a telephone call.

No fees are presently believed due. However, in the event that a fee required for the filing of this document is missing or insufficient, the undersigned attorney hereby authorizes the Commissioner to charge payment of any fees associated with this communication or to credit any overpayment to Deposit Account No. **18-0987**.

Respectfully submitted,



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